8-23-99

014084

DATA EVALUATION RECORD

PROHEXADIONE CALCIUM
(BAS 125 08 W)

Study Type: §81-4; Primary Eye Irritation

Work Assignment No. 1-02-25EE (MRID 44457739)

Prepared for
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall II
Arlington, VA 22202

Prepared by
Pesticide Health Effects Group
Sciences Division
Dynamac Corporation
2275 Research Boulevard
Rockville, MD 20850-3268

Primary Reviewer:
Christie E. Padova, B.S.

Signature: Christie E. Padova
Date: 6-22-99

Project Manager:
Mary L. Menetrez, Ph.D.

Signature: Mary L Menetrez
Date: 6/18/99

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

EPA Reviewer: Albin Kocialski, Ph.D.
Registration Action Branch 2 (7509C)

For AK Mopby 8/23/99

Work Assignment Manager: Sanjivani Diwan, PhD
Toxicology Branch 1 (7509C)

For SD Mopby 8/23/99

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS Number: 870.2400 OPP Guideline Number: §81-4

DP BARCODE: D246707 SUBMISSION CODE: S543930
P.C. CODE: 112600 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Prohexadione calcium (74.9% purity)

SYNONYMS: BAS 125 08 W; calcium salt of 3-oxido-4-propionyl-5-oxo-3-cyclohexene-carboxylate

CITATION: Poelloth, C. (1996) Study on the acute eye irritation of BAS 125 08 W in the rabbit. BASF Aktiengesellschaft, Ludwigshafen/Rhine, Federal Republic of Germany. Laboratory Project Number 13H0242/952070. January 31, 1996. MRID 44457739. Unpublished.

SPONSOR: BASF Corporation, P.O. Box 13528, Research Triangle Park, NC.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 44457739), a 52-mg portion (0.1-mL equivalent) of pulverized prohexadione calcium (74.9% purity) was placed into the conjunctival sac of the right eye of six young adult New Zealand White rabbits. Animals were observed for ocular irritation for up to 8 days following instillation.

Positive ocular irritation, characterized by moderate conjunctival redness (scores of 2) was observed in 6/6, 2/6 and 1/6 treated eyes 24, 48, and 72 hours, respectively, following instillation. No corneal or iridial effects were observed, and all conjunctival irritation (positive and otherwise) subsided by day 8. In this study, **prohexadione calcium is a mild to moderate ocular irritant** and is classified as **TOXICITY CATEGORY III** based on the positive conjunctival irritation observed through 72 hours.

This study is classified **acceptable (§81-4)** and satisfies the guideline requirement for a primary dermal irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: Prohexadione calcium (BAS 125 08 W)
   Description: Light brown granules
   Lot/Batch #: AF 284-79
   Purity: 74.9%
   CAS #: 127277-53-6

2. Vehicle: None employed

3. Test animals: Species: Rabbit
   Strain: New Zealand White (SPF)
   Age: Young adult
   Weight: 3.20-3.99 kg (combined sexes)
   Source: Dr. K. Thomae GMBH, Biberach, Federal Republic of Germany
   Acclimation period: ≥ 1 Week
   Diet: Kliba-Labordiaet 341, Klingentalmuehle AG Kaiseraugst, Switzerland, approximately 130 g/animal/day
   Water: Tap water, 250 mL/animal/day
   Housing: One animal/cage in stainless steel wire mesh cages
   Environmental conditions:
   Temperature: 20-24 °C
   Humidity: 30-70%
   Air changes: Not specified
   Photoperiod: 12-hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: July 24 - August 1, 1995

2. Animal assignment and treatment: A 52-mg portion (0.1-mL equivalent) of pulverized prohexadione calcium was placed into the conjunctival sac of the right eye of six young adult New Zealand White rabbits (five male and one female). The left eye of each animal served as an untreated control. The animals were observed for ocular irritation at 1, 24, 48, and 72 hours and 8 days following instillation. Ocular irritation was graded using the table outlined in OECD Guideline 405 (same as the Draize scale). Following the 24-hour observation, all treated eyes were washed with water.

Animals were also observed for clinical signs of toxicity and/or mortality once daily during the 8-day study.

II. RESULTS AND DISCUSSION:

A. Clinical observations: The incidence of positive ocular irritation is presented in Table 1. One hour following instillation, slight conjunctival redness (score of 1) was observed in 6/6 eyes, very slight conjunctival chemosis (score of 1) was observed in 4/6 eyes, and slight to moderate conjunctival discharge (scores of 1-2) was observed in 6/6 eyes. By 24 hours, moderate conjunctival redness (score of 2) developed in 6/6 eyes and very slight conjunctival chemosis persisted in 3/6 eyes; all discharge had subsided by 24 hours. No corneal or iridial changes were observed during the study, and all conjunctival irritation (positive and otherwise) subsided by day 8. In this study, prohexadione calcium is a mild to moderate ocular irritant.

TABLE 1. Incidence of Positive Ocular Effects

Observations	Number "Positive"/Number Tested				
	Hours				Days
	1	24	48	72	8
Conjunctivae					
Redness	---	6/6	2/6	1/6	---
Chemosis	---	---	---	---	---
Discharge[a]	5/6	---	---	---	---

--- No positive observations.

[a] Discharge is not included in evaluating a positive reaction; however, scores of ≥2 are included in this table.

B. Deficiencies: There were no deficiencies that affected the results of this study.